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PATENT APPLICATION
Docket No. 16778.5a.1.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of		)
		)
	Ole Thastrup et al.	)
		)
Serial No.:	10/072,036	)
		) Group Art
Confirmation No.:	3012	) Unit
		) 1633
Filed:	February 5, 2002	)
		)
For:	A METHOD FOR EXTRACTING QUANTITATIVE INFORMATION RELATING TO AN INFLUENCE ON A CELLULAR RESPONSE	)
		)
Examiner:	Michael D. Burkhart	)
		)
Customer No.:	022913	)

AMENDED SUMMARY OF CLAIMED SUBJECT MATTER SECTION APPEAL BRIEF OF APPELLANT

Mail Stop Appeal Brief-Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

This is an amended Summary Of Claimed Subject Matter (Section V) for the appeal to the Board of Patent Appeals and Interferences (the "Board") from the Notice of Non-Compliant Appeal Brief mailed October 21, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The Appellant's invention is a method of using a new "hybrid polypeptide" for screening compounds of a compound library to detect new biologically active compounds, which may be useful as new drugs (paragraphs [0001, 0013, and 0027]).[1] In claim 46, the new "hybrid polypeptide" of the present invention includes a "luminophore" portion and a portion that is "a subunit of a biologically active polypeptide affecting intracellular processes, which subunit exhibits a biological activity of the [biologically active] polypeptide." In claims 44 and 45, the new "hybrid polypeptide" includes a "luminophore" portion and a portion that is a "subunit of a component of an intracellular pathway affecting intracellular processes, which subunit exhibits a biological activity of the component." The specification teaches that "a component of an intracellular pathway" is a biologically active polypeptide (paragraph [0060]).

As a background, other types of "hybrid polypeptides" have been described in the Carey reference[2] and the Htun reference[3] (paragraph [0010]). The hybrid polypeptides of Htun and Carey each include a luminophore polypeptide linked to a full, natural protein of interest, not to a subunit of such a protein.

The Carey and Htun references, which have substantially the same teachings as one another, validate that hybrid polypeptides having a luminophore and a full, natural protein of interest translocate similarly to the full, natural protein. Specifically, these references show that a hybrid polypeptide (GR-GFP) with a luminophore (GFP) and a full, natural protein of interest (GR) translocated similar to the natural protein (GR) by using well-known compounds (e.g., dexamethasone, etc.) that had well-established biological activity on the natural GR protein. That is, the well-known compounds with the well-known biological activity of modulating the translocation of the natural GR protein similarly modulated the translocation of the GR-GFP hybrid polypeptide. The hybrid polypeptides of Htun and Carey do not include a "subunit of a component of an intracellular pathway affecting intracellular processes, which subunit exhibits a

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[1] For convenience, the claimed subject matter is summarized with reference to the pre-grant publication of the application having publication number US 2003/0082564.

[2] Evidence Using A Green Fluorescent Protein-Glucocorticoid Receptor Chimera that the RAN/TC4 GTPase Mediates An Essential Function Independent Of Nuclear Protein Import, KL Carey et al., *The Journal of Cell Biology*, Vol. 133, No. 5, June 1996, pp. 985-996; hereinafter, "Carey."

[3] Visualization Of Glucocorticoid Receptor Translocation And Intranuclear Organization In Living Cells With A Green Fluorescent Protein Chimera, H. Htun et al., *Proc. Natl. Acad. Sci. USA*, Vol. 93, May 1996, pp 4845-4850; hereinafter, "Htun."

biological activity of the component" as required by claims 44-45, nor a "subunit of a biologically active polypeptide affecting intracellular processes, which subunit exhibits a biological activity of the polypeptide" as required by claim 46.

Claim 44 recites:

> A method for screening (paragraphs 0013-0014) a library of compounds (paragraph 0027 and 0103) to detect a biologically active compound (paragraphs 0013, 0059, and 0118) by detecting intracellular translocation (paragraphs 0014, 0026, 0060, and 0063 and Figures 1-3, 7, and 12) of a subunit (paragraphs 0041-0055) of a component (paragraphs 0041-0055) of an intracellular pathway affecting intracellular processes (paragraph 0105), which subunit exhibits a biological activity of the component (paragraphs 0041-0054, 0117, and 0146), comprising:
>
> (a) culturing one or more cells (paragraphs 0015-0019 and 0112) containing a nucleotide sequence (paragraph 0122) coding for a hybrid polypeptide (paragraphs 0013 and 0040-0057) comprising a luminophore (paragraphs 0020-0023, 0104, and 0107) linked to the subunit (paragraphs 0040-0057) under conditions permitting expression of the nucleotide sequence (paragraphs 0151-0152, 0190, and 0212),
>
> (b) incubating the one or more cells with at least one compound of the library of compounds (paragraphs 0018-0019, 0022, 0077, 0170, and 0215),
>
> (c) screening the library of compounds to determine whether the at least one compound of the library of compounds has a biological function or biological effect on the subunit in the one or more cells (paragraphs 0058-0061, 0171-0175, 0180-0183, and 0215), wherein translocation of the subunit in response to the at least one compound of the library of compounds determines that the at least one compound has a biological function or biological effect on the subunit (paragraph 0060), and
>
> (d) measuring the light emitted from the luminophore in the incubated one or more cells (paragraphs 0029-0036, 0153-0167, 0192, and 0214) and determining a variation with respect to the emitted light from said luminophore (paragraphs 0038-0039, 0193, 0196-202, and 0216 and Figures 1-12), such variation being

indicative of the translocation of the subunit in said one or more cells and said translocation being indicative that said at least one compound of the library of compounds to be screened is biologically active with the component (paragraphs 0012-0014, 0026-0027, and 0194).

Claim 45 recites:

A method for screening (paragraphs 0013-0014) a library of compounds (paragraph 0027 and 0103) to detect a biologically active compound (paragraphs 0013, 0059, and 0118) by detecting intracellular translocation (paragraphs 0014, 0026, 0060, and 0063 and Figures 1-3, 7, and 12) of a subunit (paragraphs 0041-0057) of a component (paragraphs 0041-0055) of an intracellular pathway affecting intracellular processes (paragraph 0105), which subunit exhibits a biological activity of the component (paragraphs 0041-0054, 0117, and 0146), comprising:

(a) culturing one or more cells (paragraphs 0015-0019 and 0112) containing a nucleotide sequence (paragraph 0122) coding for a hybrid polypeptide (paragraphs 0013 and 0040-0057) comprising a luminophore (paragraphs 0020-0023, 0104, and 0107) linked to the subunit (paragraphs 0040-0057) under conditions permitting expression of the nucleotide sequence (paragraphs 0151-0152, 0190, and 0212),

(b) incubating the one or more cells with at least one compound of the library of compounds (paragraphs 0018-0019, 0022, 0077, 0170, and 0215),

(c) screening the library of compounds to determine whether the at least one compound of the library of compounds has a biological function or biological effect on the subunit in the one or more cells (paragraphs 0058-0061, 0171-0175, 0180-0183, and 0215), wherein translocation of the subunit in response to the at least one compound of the library of compounds determines that the at least one compound has a biological function or biological effect on the subunit (paragraph 0060), and

(d) extracting quantitative information relating to the translocation of said subunit by determining a variation in spatially distributed light emitted from

said luminophore (paragraphs 0038-0039, 0193, 0196-202, and 0216 and Figures 1-12), such variation being indicative of the translocation of the subunit in said one or more cells and said translocation being indicative that said at least one compound of the library of compounds to be screened is biologically active with the component (paragraphs 0012-0014, 0026-0027, and 0194).

Claim 46 recites:

A method for screening (paragraphs 0013-0014) a library of compounds (paragraph 0027 and 0103) to detect a biologically active compound (paragraphs 0013, 0059, and 0118) by detecting intracellular translocation (paragraphs 0014, 0026, 0060, and 0063 and Figures 1-3, 7, and 12) of a subunit (paragraphs 0041-0055) of a biologically active polypeptide (paragraphs 0041-0055) affecting intracellular processes (paragraph 0105), which subunit exhibits a biological activity of the polypeptide (paragraphs 0041-0054, 0117, and 0146), comprising:

(a) culturing one or more cells (paragraphs 0015-0019 and 0112) containing a nucleotide sequence (paragraph 0122) coding for a hybrid polypeptide (paragraphs 0013 and 0040-0057) comprising a luminophore (paragraphs 0020-0023, 0104, and 0107) linked to the subunit (paragraphs 0040-0057) under conditions permitting expression of the nucleotide sequence(paragraphs 0151-0152, 0190, and 0212),

(b) incubating the one or more cells with at least one compound of the library of compounds (paragraphs 0018-0019, 0022, 0077, 0170, and 0215),

(c) screening the library of compounds to determine whether the at least one compound of the library of compounds has a biological function or biological effect on the subunit in the one or more cells (paragraphs 0058-0061, 0171-0175, 0180-0183, and 0215), wherein translocation of the subunit in response to the at least one compound of the library of compounds determines that the at least one compound has a biological function or biological effect on the subunit (paragraph 0060),

(d) measuring the light emitted by the luminophore in the incubated one or more cells (paragraphs 0029-0036, 0153-0167, 0192, and 0214) and determining

a variation with respect to the emitted light (paragraphs 0038-0039, 0193, 0196-202, and 0216 and Figures 1-12), such result or variation being indicative of the translocation of the subunit in said one or more cells and said translocation being indicative that said at least one compound of the library of compounds to be screened is biologically active (paragraphs 0012-0014, 0026-0027, and 0194), and

(e) measuring the effect of said at least one compound of library of compounds on the inhibition/activation of biological activity of said subunit with the component (paragraphs 0012, 0038-0039, 0183, and 0196-0202 and Figures 3 and 5-6).

Independent claim 46 is similar to claims 44 and 45 in that the new hybrid polypeptide (having a luminophore and a subunit of a biologically active polypeptide) is used to screen a library of compounds to detect a new compound that has a biological function or biological effect on the subunit. The culturing, incubating, and screening steps are substantially similar to claims 44 and 45. A difference is that the "subunit" in claim 46 is specifically defined to be a "subunit of a biologically active polypeptide affecting intracellular processes, which subunit exhibits a biological activity of the polypeptide" (paragraphs [0041, 0043-0057, and 60-61]). Support in the specification of the elements of claim 46 is substantially identical to the support for claims 44 and 45.

The claims 47-54, 73-80, and 82 depend from one or more of claims 44-46, and define additional aspects of the invention. For example, these dependent claims relate to the following: extraction of quantitative information; measuring light emitted from the hybrid polypeptide; the identity of the compound to be screened; properties of the hybrid polypeptide; the cells being fixed; the cells are stably transformed to produce the hybrid polypeptide; and digital image manipulation. Support for the dependent claims is found throughout the specification, including the portions of the specification recited to support independent claims 44-46, in the Examples, and in paragraphs [0012-0014, 0029-0039, and 0059-0061].

CONCLUSIONS

The above is an amended Summary Of Claimed Subject Matter section in response to the Notice of Non-Compliant Appeal Brief mailed October 21, 2009. Based on the foregoing, Appellant respectfully requests that the Notice of Non-Compliant Appeal Brief be withdrawn and for the amended Summary Of Claimed Subject Matter be accepted.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to Deposit Account No. 23-3187 (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to Deposit Account No. 23-3178.

DATED this 17th day of November, 2009.

Respectfully submitted,

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